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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,481

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Osamu Mori

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EXAMINER

WILLIAMS, LELA

ART UNIT

PAPER NUMBER

1794

NOTIFICATION DATE

DELIVERY MODE

01/08/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/563,481	Applicant(s) MORI ET AL.	
	Examiner LELA S. WILLIAMS	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4 and 6-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4 and 6-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/9/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4 and 6-8 and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated

Freeman et al. (EP 0304115) as further explained by *Fats and Oils Formulating and Processing for Application*, hereafter O'Brien.

Regarding claim 4; Table 1 (page 5) prepares menhaden/corn oil blends in ratios of 10:90, 25:75, 50:50, and 75:25. Calculating using the 10:90 ratio, oleic acid (C18:1) is approx. 9.75 parts by weight, linoleic acid (C18:2) is approx. 21.86 parts by weight, and linolenic acid (C18:3) is approx 0.5 parts by weight per one part by weight of long chain highly unsaturated fatty acids (EPA/DHA). Menhaden oil composition is taken to comprise approx. 11.4% C18:1, 1.5% C18:2, 1.6% C18:3, and 24.6 % of EPA/DHA and corn oil composition is taken to comprise approx. 25.4% C18:1, 59.6% C18:2, and 1.2% C18:3, as shown by O'Brien.

Regarding claim 6, the ratio of the EPA and/or DHA in the composition is approx. 3% of the whole fatty acid composition. The “whole fatty acid composition” is taken to comprise oleic, linoleic, linolenic, and EPA/DHA.

Regarding claim 7 with respect to claim 4, the long chain highly unsaturated fatty acids are EPA or DHA (Table 1).

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Regarding claim 8 with respect to claim 4, the blend disclosed by Freeman et al. does not contain any added antioxidants.

Regarding claims 10 and 11 with respect to claim 4, the 10% menhaden oil blended with 90% corn oil blend shown in Table 1 (page 5) is inherently a liquid at 5°C since it contains all the distinctive properties presented in claim 4.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 2-3, 7-8, and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (EP 0304115) as further explained by *Fats and Oils Formulating and Processing for Application*, hereafter O'Brien.

Regarding claim 2, Table 1 (page 5) prepares menhaden/corn oil blends in ratios of 10:90, 25:75, 50:50, and 75:25. Calculating using the 25:75 ratio, oleic acid (C18:1) is approx. 3.5 parts by weight, linoleic acid (C18:2) is approx. 7.3 parts by weight, and linolenic acid (C18:3) is approx 0.2 parts by weight per one part by weight of long chain highly unsaturated fatty acids (EPA/DHA). Menhaden oil composition is taken to comprise approx. 11.4% C18:1, 1.5% C18:2, 1.6% C18:3, and 24.6 % of EPA/DHA and corn oil composition is taken to comprise approx. 25.4% C18:1, 59.6% C18:2, and 1.2% C18:3, as shown by O'Brien. It is noted that in this particular embodiment, the amount of linolenic acid falls outside of the presently claimed range, however in another embodiment (the 10:90 ratio) the amount of linolenic acid is shown to be approx 0.5 parts by weight. Given that Freeman does disclose that the desired amount of linolenic acid is an effective amount and the present application does not show the amount to be critical, the determination of a workable amount would have been within the ambit of one of ordinary skill in the art without undue experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The discovery of an optimum value of a known result effective variable, without producing any new or unexpected results, is within the ambit of a person of ordinary

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skill in the art. See *In re Boesch*, 205 USPQ 215 (CCPA 1980) (see MPEP § 2144.05, II.).

Therefore it would have been obvious to one of ordinary skill in the art to choose an amount of linolenic acid, including the presently claimed 0.5 parts by weight, in order to produce final product with desired properties.

Regarding claims 3 and 7, both EPA and DHA are compositions present in menhaden oil and are shown to comprise approx. 8% of the whole fatty acid in the 25:75 ratio. The “whole fatty acid composition” is taken to comprise oleic, linoleic, linolenic, and EPA/DHA. EPA and DHA are n-3 fatty acids having 20 or more carbon atoms and 3 or more double bonds. It is noted that in this particular embodiment, the amount of the long chain highly unsaturated fatty acids falls outside of the presently claimed range, however in another embodiment (the 10:90 ratio) the amount of long chain highly unsaturated fatty acids is shown to be approx 3% of the whole fatty acid composition. Given that Freeman does disclose that the desired amount of long chain highly unsaturated fatty acids is an effective amount and the present application does not show the amount to be critical, the determination of a workable amount would have been within the ambit of one of ordinary skill in the art without undue experimentation. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The discovery of an optimum value of a known result effective variable, without producing any new or unexpected results, is within the ambit of a person of ordinary skill in the art. See *In re Boesch*, 205 USPQ 215 (CCPA 1980) (see MPEP § 2144.05, II.).

Therefore it would have been obvious to one of ordinary skill in the art to choose an amount of

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long chain highly unsaturated fatty acids, including the presently claimed 3-7%, in order to produce final product with desired properties.

Regarding claim 8, the blend disclosed by Freeman et al. does not contain any added antioxidants.

Regarding claims 10 and 11, the 25% menhaden oil blended with 75% corn oil blend shown in Table 1 (page 5) is inherently a liquid at 5°C since it contains all the distinctive properties presented in claim 2.

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (EP 0304115) as further explained by *Fats and Oils Formulating and Processing for Application*, hereafter O'Brien and in view of Motoharu et al. JP 11-299420.

Regarding claim 9, Freeman et al. discloses adding antioxidants by teaching that TBHQ is known to be a more effective antioxidant in the stabilization of fish oil. Freeman is silent on the amount to use. Motoharu discloses the use of antioxidants in a fat and oil composition, and discloses 0.001-0.2% of ascorbic acids (L-ascorbic acid) is an effective amount [0006]. Given that Motoharu discloses the presently claimed amount of antioxidant being sufficient for use in an oil and fat composition, one of ordinary skill would find it obvious to incorporate said amount to improve the oxidation stability and flavor of DHA [0018].

Response to Arguments

In response to Applicants reply filed on October 9, 2009, claims 2-4 and 6-11 are pending in this application and claims 1 and 5 are canceled.

Applicant's arguments, filed October 9, 2009, with respect to the rejection(s) of claim(s) 1-3 and 7-11 under Freeman et al. and claims 4-6 under Andrade et al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Freeman et al.

Applicant argues that amount of linolenic acid is not anticipated by Freeman et al., however given that Freeman does disclose that the desired amount of linolenic acid is an effective amount in another embodiment of the invention and the present application does not show the amount to be critical, the determination of a workable amount would have been within the ambit of one of ordinary skill in the art without undue experimentation. Which is why claims 2-3 and 7-11 are now rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al.

Applicant also argues that Andrade et al. does not anticipate the amended claim range of claim 4, however the range is anticipated by Freeman et al., which is why claims 4 and 6-11 are now rejected under 35 U.S.C. 102(b) as being anticipated Freeman et al.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LELA S. WILLIAMS whose telephone number is (571)270-1126. The examiner can normally be reached on Monday to Thursday from 7:30am-5pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on 571-272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LELA S. WILLIAMS/
Examiner, Art Unit 1794

/L. S. W. /

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794